REMARKS

Claim objections

Claims 1 and 9 have been objected to for an informality. The Examiner states that the number 3 is not superscripted. As amended herein, claims 1 and 9 have the number 3 superscripted. Claim 14 has been objected to for the improper placement of a comma. As amended herein, the offending comma in claim 14 has been deleted. Withdrawal of these objections is therefore respectfully requested.

35 U.S.C. § 112, second paragraph

Claims 16-23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention (Office Action, page 3). Specifically, the Examiner states that the preamble in claims 15 and 16 recites a method for correcting hemoglobin values in blood, plasma, or serum while the claim steps only contain correction factors multiplied by plasma or serum hemoglobin values. Claims 17-22 are rejected as being dependent from claim 15 or 16.

Applicant respectfully traverses this rejection. Plasma and serum are both components of whole blood. It is a particular feature of the invention that the plasma fraction can be separated from the whole blood sample and analyzed for hemoglobin content separately. Support for this can be found in paragraphs 23 and 24 (amended) of the specification and in particular the last sentence of paragraph 26 (amended) which states "Specifically, and by way of example, the Bayer H * series of hematology analyzer instruments and the Bayer ADVIA series of hematology analyzer instrument systems (e.g., ADVIA 120) have the capability of performing

quantitative analysis on the total hemoglobin content of blood and of distinguishing the hemoglobin component derived from red blood cells from that derived from the plasma." One with ordinary skill in the art would recognize that listing correction values for only plasma and serum in the claim is merely a reflection of their being separate components of whole blood. Thus, the method steps recited are applicable to correcting interference in a blood chemistry value for blood, plasma or serum. Applicant respectfully requests withdrawal of this rejection and reconsideration of the rejected claims.

35 U.S.C. § 103(a)

Claims 1-3, 5-15, 17-22, and 24 have been rejected as being unpatentable over U.S. Pat. No. 5,631,165 ("Chupp") in view of U.S. Pat. No. 5,200,323 ("Chang") and Patent Application Publication No. 2002/0012904 ("Malin"). On September 23, 2003 Malin issued as U.S. Pat. No. 6,623,972. The applicant respectfully traverses this rejection.

As a preliminary matter, applicant respectfully points out that the application under examination, Ser. No. 09/865759, and Malin were, at the time the invention was made, owned by the same corporate entity. For support see assignments recorded 05/18/2001, Reel 011827, Frame 0933 and 05/25/2001, Reel 011858, Frame 0217. Therefore, under 35 U.S.C. § 103(c) Malin is not available as prior art in this examination.

Briefly, the present invention is directed to methods for correcting interference to hematology and clinical chemistry parameters due to the presence of exogenous blood substitutes during the analysis of whole blood, plasma and serum samples. As stated in paragraph 27 of the application, "the Bayer hematology analyzers, are able to determine separately and independently the cellular HGB (reported as Calculated HGB), as well as total hemoglobin (reported as HGB), in a whole blood sample." And further in paragraph 30 "The monitoring of

patient progress in patients who have received exogenous hemoglobin, e.g. PEG-HGB or purified hemoglobin, via transfusions, for example, is not possible with other commercially available analyzers and other methods, because these analyzers are not able to distinguish between the hemoglobin contributed by the exogenously provided hemoglobin substitute and the hemoglobin contributed by the red blood cells in a whole blood sample." Further details on analyzers having the capability to separately analyze red blood cell derived and exogenously derived HGB are given in paragraphs 42-45 of the application.

In contrast, Chupp, is directed to methods that are inapplicable to the problem solved by the present invention. The type of hemoglobin analysis described in Chupp is not able to differentiate between red blood cell derived hemoglobin and exogenously derived hemoglobin. For example see Chupp column 53 lines 65-67 and column 54 lines 1-27 where the Hemoglobin sampling procedure is outlined. The first step of the process is to place a portion of the patient sample in the lyse reagent and thereby releasing all of the intracellular HGB. If an exogenous HGB substitute was present in the sample it would now be interfering with the accurate measurement of cellular HGB and there is no way to easily correct for this interference. More specifically, Chupp at column 54 lines 19-22 and again at column 61 lines 45-50, teach formulas for MCH and MCHC which use total HGB (exogenous sources of HGB not separated prior to analysis) while claims 1 and 9 of the present application teach formulas for MCH and MCHC that use cellular HGB (exogenous and cellular HGB separated prior to analysis).

The examiner cites four examples in Chupp where use of the term "correction" is purported to suggest that "some type of interference among cells has taken place which is why correction is subsequently taking place."

In contrast, the opening sentence of Chupp states that "This invention relates in general to particle analysis." (Column 1, line 15). In addition, all of the examiner cited examples in Chupp relate to the measurement of cellular components of blood. Hemoglobin is a soluble component of blood. Sources of interference or methods for the measurement of cellular or particulate components of blood are not the same as those for soluble components. One of ordinary skill in the art would not be motivated to look to Chupp for methods of measuring exogenous hemoglobin since Chupp teaches only methods for measuring HGB within cells. For this additional reason one skilled in the art would not be motivated to look to Chupp to solve the problem of correcting interference to hematology and clinical chemistry parameters due to the presence of exogenous blood substitutes during the analysis of whole blood, plasma and serum samples.

In summary, applicant respectfully asserts that Chupp alone or in combination with Chang, does not teach or suggest the "correction of interference" required by independent claims 1, 9, and 15. Applicant respectfully requests withdrawal of this rejection and reconsideration of the rejected independent claims 1, 9, and 15. Applicant also respectfully requests withdrawal of this rejection from claims 2, 3, 5-8, 10-14, 17-22, and 24 which depend from claims 1, 9, and 15 or 16.

CONCLUSION

Based on the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the objections and rejections of claims and allowance of this application.

AUTHORIZATION

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 0708-4057. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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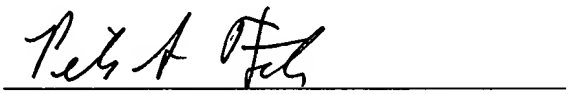
Dated: December 9, 2003 By: 

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